K022370 1/2

Medtronic Xomed
6743 Southpoint Dr. N.
Jacksonville, Florida 32216-0980

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Medtronic
XOMED

OCT 1 8 2002

2 Summary

Summary statement in accordance with the Safe Medical Devices Act (SMDA)

1.0 Date Prepared 19 July 2002

2.0 Submitter (Contact)

B. L. McDermott, RAC
Senior Regulatory Affairs Specialist
Medtronic Xomed, Inc.
Jacksonville FL 32116.0980
904.332.8562

3.0 Device Names and Classifications

Classification for the (1) FrameLock™ and (2) FrameLock™ accessories is under two generic names:

(1) Cranial drill handpiece (brace)
(2) Manual cranial drills, burrs, trephines, and their accessories

Table 1 Device Names and Classifications for FrameLock Kit

Item	REF	Device Name	Reg. Number	Reg. Class
1	960-811	FrameLock Kit	*(Listed by parts)*	II
2	960-808	FrameLock	21 CFR 882.4325	I exempt
3	960-802	Screws	21 CFR 882.4300	II
4	960-368	Guide Pin	21 CFR 882.4300	II
5	960-803	Screwdriver	21 CFR 882.4300	II
6	960-804	Drill Assembly *(current)*	21 CFR 882.4300	II
7	960-806	Sterilization Tray *(current)*	21 CFR 882.4300	II
8	960-807	Open Cannulation Nut	21 CFR 882.4325	I exempt
9	960-707	Closed Cannulation Nut	21 CFR 882.4300	II
10	960369	LandmarX Modular Drill Handle (future)	21 CFR 882.4300	II
11	960371	LandmarX Modular Drill Bit *(future)*	21 CFR 882.4300	II
12	960374	FrameLock Sterilization Tray *(future)*	21 CFR 882.4300	II

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Summary *(continued)*

4.0 Device Description

The LandmarX™ FrameLock™ kit is an optional accessory of the LandmarX Image Guided Surgical System, previously cleared in K992927

The LandmarX™ FrameLock™ kit is designed to provide a safe, reliable, compact, and minimally invasive means of direct and rigid fixation to the patient's skull for the LandmarX™ reference arc (REF # 960-632). The FrameLock™ mounts using a titanium screw entering a pilot hole drilled with stainless steel manual drill and accessories. A small percutaneous incision is adequate to install the device. The FrameLock also permits navigation using the sterile drape technique.

5.0 Indications for Use

The FrameLock™ is indicated for otorhinolaryngological and head/neck surgery where any medical condition in which the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomic head or neck structure, such as the skull, vertebrae, intranasal area, or sinus, can be identified relative to a CT or MR based model of the anatomy.

6.0 Substantial Equivalence

The drill and screws in the FrameLock kit have design, technology, features, function and intended use of manual cranial drills and their accessories with Substantial Equivalence (SE) to Medtronic hand drill and drill bits [K904283], currently marketed in the Medtronic PS Medical Ventriculostomy Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2002

Medtronic Xomed, Inc.
B. L. McDermott, RAC
Senior Regulatory Affairs Specialist
6743 Southpoint Drive, North
Jacksonville, Florida 32216-0980

Re: K022370
Trade/Device Name: Framelock™
Regulation Number: 882.4300
Regulation Name: Manual cranial drills, burrs, trephines and their accessories
Regulatory Class: II
Product Code: HBG
Dated: July 19, 2002
Received: July 22, 2002

Dear Mr. McDermott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K022370

DEVICE NAME: FrameLock

INDICATIONS FOR USE:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022370